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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/903,925

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Avi Ashkenazi

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 09/10/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/903,925

Applicant(s)
Ashkenazi et al.

Examiner
Fozia Hamud

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1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 21, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-38 and adding new claims 39-44 filed on 21 November 2001 in Paper No:2 is acknowledged.

Thus claims 39-44 are pending and under consideration

Priority

2. Priority given to some parent cases but not others:

According to the priority statement of 08/21/02, it appears that the claimed subject matter defined in the instant application is disclosed in the parent application serial no. 09/665,350, filed on 09/18/2000, which is a continuation of PCT/US00/0441, which claims priority through a series of CIP applications under 35 U.S.C. to US Provisional Application 60/066772 filed 11/24/1997. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no. 60/066772, filed 11/24-1997, because, although the amino acid sequence of PRO343 is disclosed in figure 28 (SEQ ID NO:15) of 60/066772 and antibodies binding to said polypeptide are contemplated on pages 29-35 of 60/066772, the parent application does not provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims 39-44 has an effective filing date of 07/11/2001 which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 07/11/2001 which specifically supports the particular claim limitation for

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each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 07/11/2001.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 154, line 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP § 608.01.

Claim Rejections - 35 U.S.C. § 101/112

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 39-44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 39-44 of the instant invention are directed to a an antibody that binds to the polypeptide of SEQ ID NO:263. The specification describes the polypeptide of SEQ ID NO:263 as comprising 317 amino acid residues and refers it to PRO343, (page 50, line 20-21). The PRO343 is described as having a signal sequence, N-glycosylation site, glycoaminoglycan attachment site, casein kinase II phosphorylation site, Tyrosine kinase phosphorylation site and N-myristoylation site, (see figure 98). However, besides these structural characterizations, the specification does not disclose any information regarding physiologic activity or functional characteristics of the PRO343 polypeptide. Instant specification demonstrates that PRO343 along with many of the other proteins

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disclosed by the instant specification, are expressed in lung and colon primary tumors and cell line models, (see table 9 on pages 230-234). However, it does not describe the significance of this expression, nor does it compare the expression of PRO343 in normal lung and colon tissues to the expression of said protein in the lung and colon tumors or cell lines. The specification establishes no connection between the expression of said polypeptide and developing lung or colon tumors. The specification provides no working examples as to the activity of the PRO343 polypeptide, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application, based solely it might be expressed in some primary lung or colon tumors or cell lines. Thus, since the PRO343 polypeptide lacks a specific or substantial utility, antibodies against it, also lack specific asserted utility or a well established utility.

4b. Claims 39-44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. No biological activity was assayed or determined for the PRO343 polypeptide or antibodies against it. Therefore, there is no specific and substantial asserted utility or well established for antibodies against PRO343 polypeptide. Although the specification describes the structure of PRO343 polypeptide, and one of ordinary skill in the art can make antibodies against it, the skilled artisan would not know how to use said PRO343 polypeptide or antibodies against it, because Applicants do not provide any information regarding biological activity or physiological characterization of said polypeptide.

Claim Rejections - 35 U.S.C. §102

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 39-40, 42-44 are rejected under U.S.C. § 102 (b) as being anticipated by Amrad Operations Pty. Ltd (WO 98/36054; published 20 August 1998).

Amrad Operations Pty. Ltd discloses an isolated polypeptide that shares 86.3% over all homology and 100% homology from amino acid residue 47 to amino acid residue 317 of the polypeptide of SEQ ID NO:263 of the instant application. (See attached copies of the comparison of SEQ ID NO:263 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A')). Amrad Operations Pty. Ltd also discloses an antibody, (monoclonal, polyclonal, fragment of antibody or which may be associated with a carrier molecule). Instant claims 39-40, 42-44 are drawn to an antibody (monoclonal, fragment or labeled) that binds to the polypeptide of SEQ ID NO:263. The Amrad Operations Pty. Ltd reference meets all the limitations of claims 39-40, 42-44, because the antibody disclosed in this reference would be expected to bind to the polypeptide of SEQ ID NO:263 of the instant application. Therefore, the Amrad Operations Pty. Ltd reference anticipates the instant claims 39-40, 42-44 in the absence of any evidence to the contrary.

Claim Rejections - 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

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matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amrad Operations Pty. Ltd. (WO 98/36054) in view of Carter et al. (U.S. Patent 5,821,337).

The disclosure of Amrad Operations Pty. Ltd as relating to claim 39 is discussed directly above.

However, Amrad Operations Pty. Ltd reference does not teach a humanized antibody that binds to the polypeptide of SEQ ID NO:263.

Carter et al teach humanized antibody polypeptides and methods of making and using them, (see abstract). Carter et al disclose a humanized antibody which is less antigenic in humans than non-human antibodies but retain the desired antigen binding and other desired characteristics and activities, (see column 4, lines 23-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the antibody taught by Amrad Operations Pty. Ltd, by humanizing said antibody as taught by Carter et al, because humanized antibodies can be manipulated to be less

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antigenic in humans than non-human antibodies, while retaining the desired antigen binding and other characteristics and activities. One of ordinary skill in the art would have been motivated to make humanized antibodies, because humanized antibodies are therapeutically useful and are tolerated better by potential patients.

Thus, the claimed invention as a whole was obvious over the combined prior art.

Conclusion

7. No claim is allowed.

Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursdays from 7:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
03 September 2002


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